UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE, and STEM CELL & REGENERATIVE MEDICINE INTERNATIONAL, INC.,)))
Plaintiffs,) C.A. NO. 1:17-cv-12239-ADB
v.))
IMSTEM BIOTECHNOLOGY, INC., XIAOFANG WANG, and REN-HE XU,)))
Defendants.)))

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR LEAVE TO FILE REPLY BRIEF AND FOR LEAVE TO FILE DOCUMENTS UNDER SEAL

Pursuant to L.R. 7.1(b)(3), Defendants ImStem Biotechnology, Inc., Xiaofang Wang, and Ren-He Xu (collectively, "ImStem" or "Defendants") respectfully request leave to file a 7-page Reply to Plaintiffs' Opposition to Defendants' Motion for Leave to File Amended Counterclaims (Dkt. 75), within 72 hours of this Court ruling on the instant Motion. Pursuant to L.R. 7.2 and the relevant Protective Order (Dkt. 55), Defendants also seek leave to file the reply and certain exhibits under seal.

ARGUMENT

I. Plaintiffs Have Raised a Number of New Arguments That Warrant a Response

Plaintiffs have filed a 20-page opposition brief that includes 11 argument headings, 29 cases, and 16 exhibits totaling 200 pages, signed by five lawyers. (Dkt. 75). The scale of the brief alone warrants a reply. The scale of the brief also underscores the context of the underlying Motion and case. *Cf. Nikitine v. Wilmington Trust Co.*, 715 F.2d 388, 390 (1st Cir. 2013)

("everything depends on context"); *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 57 (1st Cir. 2008) ("[i]n assessing delay, [e]ach case ... turn[s] on its own circumstances"). Indeed, Plaintiffs have had more lawyers working on the case than ImStem has employees.

The Plaintiffs' opposition brief includes a large "futility" argument (itself in the nature of an opposition, ordinarily raised by the non-movant) that warrants a response. Oppn. at 10-15. Plaintiffs' argument is enormously complicated and turns on disputed facts regarding such arcana as the potency of bone-marrow-derived MSCs, *id.* at 12, the novelty of measuring interleukin-6 cytokines, *id.*, or whether "mitotic inactivation" was known in the relevant art, *id.* at 13. This "futility" argument, in other words, goes to contested inventorship facts. Plaintiffs are using the Opposition as a vehicle for moving to dismiss (again); ImStem should be permitted to respond.

ImStem likewise deserves a chance to respond to Plaintiffs' arguments relating to the Statute of Limitations affirmative defense. *Id.* at 18-19. The defense turns on Plaintiffs' documents the Defendants could not have seen at the time of the Answer (documents marked "Highly Confidential" to this day) – and long known to the Plaintiffs – yet Plaintiffs express surprise at Defendants having found them and contend the Defendants should not be permitted to respond to that alleged surprise in a reply brief. Defendants are prepared to explain and attach the relevant documents under seal, a process (and thus expense) that they had hoped to avoid in light of the fact that all of the documents were already known to the Plaintiffs. Defendants will also explain the relevant timeline with respect to when they received information.

¹ Defendants offered to file an amended brief to explain the defense and flag individual documents during the status conference (Dkt. 73); the Court said words to the effect that everyone was "now on notice." More generally, the relevant procedural history is set forth in the Memo. In Supt. of Def.'s Mot. for Leave to file Amended Counterclaims (Dkt. 71). The parties did not start producing documents until January 30, 2019.

As urgently, Defendants need a reply brief to respond to Plaintiffs' novel argument that a claim that could not be raised in one action (because it was "too late" to litigate it) may nevertheless be barred in another action on the ground that it was, apparently, litigated in the first action (from which it was barred). Oppn. at 12-13. Left unanswered, the Opposition invites a ruling that would prejudice Defendants (who intend to file a separate action if the underlying Motion is denied).

II. Plaintiffs Have Raised a Number of Factual Inaccuracies That Warrant a Response

Plaintiffs have made a number of new factual assertions – many wrong, many dressed up in heated language – that warrant a response. Plaintiffs produced their privilege log two days ago, *i.e.* about a week after the underlying Motion, raising additional bases to assert the statute of limitations defense, yet Plaintiffs would deny Defendants the chance to explain why all of this was somehow not apparent in 2017. The Court would benefit from a response.

By way of further example, Plaintiffs prominently discuss a document that they produced on July 26, 2019, as well as July 29, 2019 deposition testimony from Dr. Wang, yet another portion of Dr. Wang's new testimony refutes Plaintiffs' assertions. Defendants wish to correct the record.

III. Events Since the Underlying Motion was Filed Justify a Reply Brief

Somewhat unusually, events since the underlying Motion also favor a reply brief. ² The underlying Motion to Amend was filed on July 22, 2019 (Dkt. 70). Two depositions have taken place since then. On July 26, 2019, Plaintiffs made third-party Dr. Shi-Jiang Lu (who was

² Document discovery was slated to end June 28, 2019 (Dkt. 56) but Plaintiffs have not yet produced documents concerning Astellas' acquisition of co-Plaintiff SCRMI in June 2019 (most of which presumably pre-date the close of discovery). Plaintiffs have likewise not yet scheduled a 30(b)(6) witness for over a dozen topics. Plaintiffs offered the 30(b)(6) witness on July 23, 2019, but only for half a day, on short notice, at a time when counsel for Defendants was unavailable.

represented by Plaintiffs' counsel) available for deposition. On July 29, 2019, Defendants made Dr. Wang – the lead inventor – available for a second deposition, to answer questions regarding documents and/or issues that had arisen since his earlier (June 14, 2019) deposition – including Defendants' proposed amended Counterclaim.³ In their Opposition, Plaintiffs have cited testimony from the new Wang deposition without giving Defendants a chance to respond or provide counter-designations. Likewise, Dr. Lu made statements that were (1) inconsistent with earlier testimony from Plaintiffs' witnesses regarding inventorship; and (2) relevant to the Defendants' proposed Counterclaims.⁴ The Court would benefit from a complete record.

IV. A Reply Brief Will Not Cause Substantial Delay

Defendants are prepared to file a short reply brief within 72 hours of an Order on the instant Motion. A quick, targeted reply brief will not delay matters. Indeed, a reply could speed the Court's passage through Astellas's 20-page Opposition. Most of its arguments will fall away with a small amount of response.

Indeed, Plaintiffs blanket opposition to a reply is odd.⁵ For starters, forcing the Defendants to file the instant motion has caused more cost and delay than a simple assent would have done. *Cf.* Oppn. at 18 (Plaintiffs oppose reply "because of the Court's interest in expeditious resolution of the [underlying] motion"). The Court would have been free to deny any assented-to motion and/or disregard the reply, but at least would have been spared the instant briefing.

³ Plaintiffs did not use the 4 hours agreed upon, concluding at a little over 3 hours and 20 minutes.

⁴ In an effort to avoid (still more) motion practice, this motion does not contain quotes or information that the Plaintiffs have designated "Highly Confidential." Defendants must necessarily speak in veiled terms. The Reply brief, filed under seal, will include specifics.

⁵ In the parties' meet-and-confer, counsel for the Defendants conveyed the precise relief sought here, including the 7-page limit and quick turnaround. Plaintiffs still opposed.

V. Astellas's Opposition Necessitates a Response Involving "Highly Confidential" Documents Filed Under Seal

In the event the Court grants the Defendants leave to file a reply brief, Defendants also request leave Pursuant to L.R. 7.2 and the Protective Order (Dkt. 55) to file portions of the brief and exhibits – designated "Confidential" or "Highly Confidential" by the parties – under seal. *See* Dkt. 55 (Order) at 15-16. Specifically:

- 1. Excerpts of the June 18, 2019 deposition of Erin Kimbrel;
- 2. Excerpts of the June 24, 2019 deposition of Nicholas Kouris;
- 3. Excerpts of the July 2, 2019 deposition of Jianlin Chu;
- 4. Excerpts of the July 29, 2019 deposition of Xiaofang Wang;
- 5. Five or fewer Astellas internal emails and their attachments; and
- 6. Excerpts from Plaintiffs' July 29, 2019 Privilege Log.

The deposition excerpts respond to arguments made in the Opposition. The internal communications elucidate the time-bar issues long known to Astellas. Pursuant to L.R. 7.2(a), Defendants believe the materials can and should be de-designated and published immediately, but in the interest of speed proposes that the reply brief be kept under seal through trial. *Cf.* Protective Order at 7, §3(b) (burden is on designating party).

Counsel for Plaintiffs has indicated that, in the event the Court grants Defendants leave to file a reply brief, Plaintiffs do not oppose placing confidential portions of the reply and exhibits under seal.

WHEREFORE, for the reasons set forth more fully above, Defendants respectfully request the Court grant its Motion for Leave to File a Reply Brief and to File Documents Under Seal.

Dated: August 1, 2019 Respectfully submitted,

IMSTEM BIOTECHNOLOGY, INC., REN-HE XU and XIAOFANG WANG,

By their Attorneys,

/s/ Timothy R. Shannon

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

I hereby certify that, on August 1, 2019, counsel for Defendants conferred with Counsel for Plaintiffs in a good faith effort to narrow or resolve the issues raised in the instant motion. Counsel for Plaintiffs indicated that (i) Plaintiffs oppose the Defendants' request to file a reply brief; and (ii) in the event the Court grants the Defendants leave to file a reply brief, Plaintiffs do not oppose placing confidential portions of that brief and exhibits under seal.

Dated: August 1, 2019 /s/ Timothy R. Shannon
Timothy R. Shannon

CERTIFICATE OF SERVICE

I hereby certify that I caused this document to be filed through the CM/ECF system, to be sent electronically to the registered participants, and paper copies to be sent to those indicated as nonregistered participants on the date below.

Dated: August 1, 2019 /s/ Timothy R. Shannon

Timothy R. Shannon